

**PATENT**

**Attorney Docket No.: 18184-0003 US**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re:	Patent application of	:
	Herbert W. Harris et al.	:
		:
		: Group Art Unit:
Serial No.:	Not Yet Assigned	: Not Yet Assigned
		:
Filed:	Herewith	: Examiner:
		: Not Yet Assigned
For:	PHARMACEUTICAL COMPOSITION OF 1-(3-	:
	HYDROXY-4-METHOXYPHENYL)-4-	:
	METHYL-5-ETHYL-7,8-DIMETHOXY-5H-2,3-	:
	BENZODIAZEPINE AND USES THEREOF	:

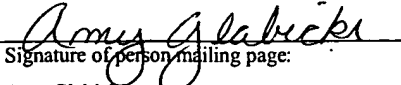
**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, submitted herewith are copies of the references listed in the accompanying PTO-1449 Forms.

The Examiner is respectfully requested to review the items listed on the attached forms and make them of record in the instant application as required by M.P.E.P. §609. It is requested that the Examiner initial the enclosed duplicate Form 1449, and return one copy to the undersigned.

<p style="text-align: center;"><b>CERTIFICATE OF MAILING</b> <b>UNDER 37 C.F.R. 1.10</b></p> <p><b>EXPRESS MAIL Mailing Label Number:</b> <u>EV 335631181 US</u></p> <p><b>Date of Deposit:</b> <u>December 3, 2003</u></p> <p>I hereby certify that this correspondence, along with any paper referred to as being attached or enclosed, and/or fee, is being deposited with the United States Postal Service, "EXPRESS MAIL-POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10, on the date indicated above, and addressed to: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p> <p style="text-align: right;"> _____ Signature of person mailing page: Amy Glabicki _____ Type or print name of person</p>
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This Statement should not be construed as a representation that the cited references are material or that more relevant prior art does not exist.

This Statement is being submitted before receipt of any office action on the merits. Thus, no fee is due for the filing of this paper. However, if a fee is due, please charge deposit account 50-0573.

Respectfully submitted,

HERBERT W. HARRIS et al.

BY



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<b>SUBSTITUTE FORM PTO-1449</b> <b>U.S. DEPARTMENT OF COMMERCE</b> <b>PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE STATEMENT</b>	<b>ATTY. DOCKET NO.</b> 18184-0003US	<b>SERIAL NO.</b> Not Yet Assigned
	<b>APPLICANT:</b> Herbert W. Harris et al.	
	<b>FILING DATE</b> Not Yet Assigned	<b>GROUP</b> Not Yet Assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
	AA	3,736,315	5/29/83	Jéno Kórosi et al.	540	567	
	AB	4,322,346	3/30/82	Jéno Kórosi et al.	540	567	
	AC	4,423,044	12/27/83	Jéno Kórosi et al.	514	221	
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	AG	5,204,343	4/20/93	Ferenc András et al.	514	221	
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		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AP	0 492 485 A1	7/1/92	Europe				
	AQ	178516	3/31/83	Hungary			X	
	AR	WO 92/11262	7/9/92	PCT				

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 18184-0003US	SERIAL NO. Not Yet Assigned
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AT	R. Sladká et al., "A Placebo-controlled Clinical Trial with Tofizopam * in the Treatment of Anxiety Neurosis" Divisions of Psychiatry, District Institutes of National Health, Prague, 2 and 4; Psychiatric Department and Psychiatric Research Unity, Medical Scholl of Charles University, Prague, Czechoslovakia, pages 176-180
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AV	E. Tomori et al., "Investigation of the Metabolites of Tofizopam in Man and Animals by Gas-Liquid Chromatography-Mass Spectrometry", Journal of Chromatography, 241 (1982), pages 89-99.
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AX	Sharon Pellow et al., "The Effects of Tofisopam, a 3,4-Benzodiazepine, in Animal Models of Anxiety, Sedation, and Convulsions", Drug Development Research 7, pages 61-73 (1986).
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EXAMINER

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**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, Etc.)

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	BG	A. Pakkanen et al., "Comparative Study of the Clinical Effects of Tofizopam, Nitrazepam and Placebo as Oral Premedication", British Journal of Anaesthetics, pages 1009-1012.
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	BM	L. Petőcz et al., "The Main Pharmacological Characteristics of Grandaxin (Tofizopam, Egypt-341), Hungarian Medical Journal, Vol. 23, No. 4, (1975), pages 134-138.
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	BP	Clinical Evaluation of Tofisopam (Grandaxin) on Gastro-intestinal Various Unidentified Complaints. Aoyagi Toshio, Kubo Akiyoshi, Sano Masaaki, Kashiwazaki Kazuo, Kojima Toshiya, Nishizato Yoshinori, Koizumi Kazumasa, Yoshioka Masahiro and Miyake Shozo. Japanese Pharmacology & Therapeutics, 1992, Vol. 20, No. 2, pages 657-667. English translation provided.
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	BV	Sergey V. Kalashnikov et al., "Immunomodulating Effects of Tofizopam (Grandaxin®) and Diazepam in Vitro", Mediators of Inflammation, Vol. 11, (2002), pages 53-59.
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